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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/598,697 | 09/26/2007 | Allen John Pearson | PB60448USw | 9067 |
| 23347 7590 11/23/2011 GLAXOSMITHKLINE GLOBAL PATENTS FIVE MOORE DR., PO BOX 13398 MAIL STOP: C2111.2F RESEARCH TRIANGLE PARK, NC 27709-3398 | | | EXAMINER SKORUPA, VALERIE LYNN | |
| | | | ART UNIT 3771 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/598,697 | Applicant(s) PEARSON ET AL. | |
| | Examiner VALERIE L. SKORUPA | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 158-247 is/are pending in the application.
- 5a) Of the above claim(s) 201-247 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 158-200 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 08 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/8/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 158-200 (Species A) in the reply filed on September 23, 2011 is acknowledged.

Information Disclosure Statement

1. The information disclosure statement filed September 8, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Copies of the following cited documents were not provided: cite no. 21, 24, 28, 30, 31, 34, 37, 66, 70, 73, and 74.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 158-168, 170-175, 179-183, 188, and 193 are rejected under 35 U.S.C. 102(b) as being anticipated by Fowler (US Patent No. 3,404,681).**

4. As to claim 158, Fowler discloses an inhaler (Fig. 1) comprising: a housing 6 in which a medicament formulation is received and a dispensing member 1 is relatively movable to cause dispensing of a dose of the medicament formulation for inhalation by

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a user through a dispensing outlet 7 of the housing 6 (col. 4, ln. 17-27); and a restricting member 30 movable between a first position (removed from the mouthpiece 7) which enables relative movement between the dispensing member 1 and the housing 6 for dispensing of the dose of the medicament formulation, and a second position (inserted into the mouthpiece 7) in which the restricting member 30 restricts relative movement between the dispensing member 1 and the housing 6 such that dispensing of the dose of the medicament formulation is prevented (col. 3, ln. 73 – col. 4, ln. 4); characterized in that the restricting member 30 enters the housing 6 through the dispensing outlet 7 to be disposed in its second position (see Fig. 1).

5. As to claim 159, Fowler discloses that the restricting member 30 is releasably attachable to the housing 6 in its second position (cap 28 can be removed, col. 4, ln. 11).

6. As to claim 160, Fowler discloses that the restricting member 30 is part of an accessory 28 which is attachable to the housing 6 (col. 3, ln. 69-74).

7. As to claim 161, Fowler discloses that the accessory 28 is attachable to the dispensing outlet 7 of the housing 6 (col. 3, ln. 73 - col. 4, ln. 2).

8. As to claim 162, Fowler discloses that the dispensing member 1 is a container unit in which the medicament formulation is contained (col. 3, ln. 39).

9. As to claim 163, Fowler discloses that the restricting member 30 is provided on a closure 28 positionable to close the dispensing outlet 7 and wherein when the closure 28 is positioned to close the dispensing outlet 7, the restricting member 30 enters the

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housing 6 through the dispensing outlet 7 to be disposed in its second position (col. 3, ln. 73 - col. 4, ln. 6).

10. As to claim 164, Fowler discloses that in use the dose of the medicament formulation is dispensed from the container unit 1 when the container unit 1 moves relative to the housing 6 in a first direction (col. 4, ln. 17-27) and wherein the restricting member in its second position restricts movement of the container unit 1 in the first direction (col. 3, ln. 73 – col. 4, ln. 2).

11. As to claim 165, Fowler discloses that in its second position the restricting member 30 restricts relative movement between the container unit 1 and the housing 6 through physical engagement of the restricting member 30 with the container unit 1 (col. 3, ln. 73 – col. 4, ln. 2).

12. As to claim 166, Fowler discloses that the restricting member 30, in its second position, is disposed in front of a leading end of the container unit 1 (see Fig. 1).

13. As to claim 167, Fowler discloses that the housing 6 has an axis along which the container unit 1 is movable relative to the housing 6 to dispense the dose of the medicament formulation and the restricting member 30, in its second position, extends laterally to the axis to restrict said relative movement (see Fig. 1).

14. As to claim 168, Fowler discloses that the restricting member 30 is configured as an arm structure (arms 32, see Fig. 2, col. 3, ln. 70-73).

15. As to claim 170, Fowler discloses that the container unit 1 is a dispensing container unit having first 3 and second parts 1 which are movable relative to one another, said relative movement causing dispensing of the dose of the medicament

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formulation from the dispensing container unit, and wherein the housing 6 has a support 10 for supporting the first part 3 of the dispensing container unit in a stationary position relative to the housing 6 so that, in use, the second part 1 is able to move in the housing 6 relative to the first part 3 to dispense the dose of the medicament formulation (col. 4, ln. 11-27), and wherein the restricting member 30, in its second position, restricts the movement of the second part 1 relative to the first part 3 to prevent dispensing of the dose (col. 3, ln. 73 – col. 4, ln. 4).

16. As to claim 171, Fowler discloses that one of the first and second parts is a dispensing outlet member 3 of the dispensing container unit (valve) and the other part is a container member 1 containing the medicament formulation (aerosol can).

17. As to claim 172, Fowler discloses that the first part is the dispensing outlet member 3 and the second part is the container member 1 and wherein the support 10 is adapted in use to direct the output of the dispensing outlet member 3 out of the housing 6 through the dispensing outlet 7 thereof (col. 4, ln. 21-27).

18. As to claim 173, Fowler discloses that the inhaler is a pressurized metered dose inhaler (pMDI) with the second part 1 being a pressurized container member containing therein the medicament formulation under pressure and the first part being a valve stem 3 of a metering valve for releasing a metered dose of the pressurized medicament formulation from the dispensing container unit upon relative movement between the pressurized container member and the valve stem (col. 4, ln. 12-27).

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19. As to claim 174, Fowler discloses that the restricting member 30 comprises a pair of arms 32 (Fig. 2) that straddle the support 10 when the restricting member 30 is in the second position (col. 4, ln. 4-6).

20. As to claim 175, Fowler discloses that the support 10 is a stem block for receiving the valve stem 3 (see Fig. 1, col. 3, ln. 59-60).

21. As to claim 179, Fowler discloses that the closure 28 is movable between a closing position (Fig. 1), engaged with the housing 6, in which it closes the dispensing outlet 7 and places the restricting member 30 in the second position (col. 3, ln. 73 – col. 4, ln. 4), and an opening position in which it opens the dispensing outlet 7 and places the restricting member 30 in its first position (col. 4, ln. 11-12).

22. As to claim 180, Fowler discloses that the closure 28 is detachably mountable on the housing 6 (col. 4, ln. 11-12).

23. As to claim 181 and 183, Fowler discloses that in use the closure 28 is moved from its closing position to its opening position by detaching the closure 28 from the housing 6 (col. 4, ln. 11-12).

24. As to claim 182, Fowler discloses that the closure 28 is releasably engageable with the dispensing outlet 7 of the housing 6 to close the dispensing outlet 7 (col. 3, ln. 73 - col. 4, ln. 2).

25. As to claim 188, Fowler discloses that the container unit 1 further has a metering mechanism 3 for dispensing a metered dose of the medicament formulation on movement of the container unit 1 relative to the housing 6 (col. 4, ln. 12-27).

26. As to claim 193, Fowler discloses that the dispensing outlet 7 of the housing is in a nozzle 7 configured for insertion into a nostril or a mouth of a human or animal body (mouthpiece, col. 3, ln. 46-49).

27. **Claims 158, 162, 163, 194, and 197-199 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryden (US Patent No. 3,622,053).**

28. As to claim 158, Ryden discloses an inhaler (Fig. 1-4) comprising: a housing 10, 12 in which a medicament formulation is received and a dispensing member 2 is relatively movable to cause dispensing of a dose of the medicament formulation for inhalation by a user through a dispensing outlet 34 of the housing 10, 12 (col. 3, ln. 35-41); and a restricting member 40 movable between a first position which enables relative movement between the dispensing member 2 and the housing 10, 12 for dispensing of the dose of the medicament formulation (col. 3, ln. 32-41), and a second position in which the restricting member 40 restricts relative movement between the dispensing member 2 and the housing 10, 12 such that dispensing of the dose of the medicament formulation is prevented; characterized in that the restricting member 40 enters the housing 10, 12 through the dispensing outlet 34 to be disposed in its second position (col. 3, ln. 20-24).

29. As to claim 162, Ryden discloses that the dispensing member 2 is a container unit in which the medicament formulation is contained (col. 2, ln. 52-57).

30. As to claim 163, Ryden discloses that the restricting member 40 is provided on a closure 40 positionable to close the dispensing outlet 34 and wherein when the closure is positioned to close the dispensing outlet 34, the restricting member enters the

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housing 10, 12 through the dispensing outlet 34 to be disposed in its second position (see Fig. 2, col. 3, ln. 20-24).

31. As to claim 194, Ryden discloses a connector 46, 47 which connects the housing 10, 12 and the closure 40 to one another (see Fig. 3, col. 3, ln. 5-8).

32. As to claim 197, Ryden discloses that the connector 46, 47 comprises: a first component (recesses in walls 36, 38, see Fig. 3, col. 3, ln. 7-8), attached to the housing 10, 12; and a second component 46, 47, attached to the closure 40; wherein the components are capable of relative movement between a contracted position, in which the closure 40 closes the dispensing outlet 34, and an extended position, in which the closure 40 is spaced from the dispensing outlet 34 (see Fig. 2).

33. As to claim 198, Ryden discloses that one of said components comprises a pin 46, 47 and the other comprises a slot (recesses in wall 36, 38, see Fig. 3), wherein the pin 46, 47 is captive within the slot and capable of movement within it (col. 3, ln. 5-8).

34. As to claim 199, Ryden discloses that at least one of the components comprises hinging means (Fig. 2, col. 3, ln. 5-8).

Claim Rejections - 35 USC § 103

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

36. **Claims 169 and 176-178 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryden, in view of Meshberg (US Patent No. 6,382,463).**

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37. As to claim 169, Ryden discloses the claimed invention except that the restricting member is configured as a clip which, in its second position, clips to the housing and/or the container unit to retain the restricting member in its second position. However, Mesh berg teaches a restricting member which is configured as a clip which clips into the housing to retain the restricting member in its closure position (projection 915 clips into recess 917, see Fig. 5, col. 3, ln. 56-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Ryden so that the restricting member is configured as a clip as taught by Meshberg in order to provide a means for retaining the restricting member in place in its closure position.

38. As to claim 176-178, the modified inhaler of Ryden discloses that the clip detachably engages a step in the support of the housing (Meshberg teaches the clip engaging the nozzle outlet, see Fig. 5, col. 3, ln. 56-62).

39. **Claims 184-187 and 189-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler, in view of Marx (US Patent No. 7,464,708).**

40. As to claims 184-186 and 189, Fowler discloses the claimed invention except that the inhaler further comprises an indicator in the container unit with a visual display wherein the indicator is adapted to update the visual display in response to movement of the container unit relative to the housing. However, Marx teaches an inhaler 100 (Fig. 8a) with an indicator 50 (Fig. 4, Fig. 7) on a container unit 1 of the inhaler and which includes a visual display (at 67, Fig. 5) wherein the indicator 50 updates the

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visual display 67 in response to movement of the container unit 1 relative to the inhaler housing 20 (col. 16, ln. 12-24).

41. As to claim 187, the modified inhaler of Fowler discloses the claimed invention including that the restricting member in its second position restricts movement of the container unit and the housing such as to prevent updating of the display (since Fowler's restricting member 30 prevents the container 1 from being moved relative to the housing 6, it would also prevent updating of the display).

42. As to claims 190-192, the modified inhaler of Fowler discloses the claimed invention including that the indicator is mounted on the container member of the container unit, the indicator is mounted at the leading end of the container unit and that the indicator is comprised in the second part of the container unit (see Fig. 4, Fig. 7 of Marx).

43. **Claims 194 and 196-199 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler, in view of Arghyris et al (US Patent No. 6,261,274).**

44. As to claim 194, Fowler discloses the claimed invention except that the inhaler has a connector which connects the housing and the closure to one another. However, Arghyris teaches a connector 22 which connects a closure 21 to a housing of a dispenser (col. 5, ln. 7-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Fowler to include the connector as taught by Arghyris in order to prevent loss of the closure.

45. As to claim 196, the modified inhaler of Fowler discloses that the connector is telescopic (see Arghyris, col. 5, ln. 16-21).

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46. As to claim 197, the modified inhaler of Fowler discloses that the connector 22 (Fig. 3 of Arghyris) comprises: a first component 25, attached to the housing; and a second component 22, attached to the closure 21; wherein the components are capable of relative movement between a contracted position, in which the closure 21 closes the dispensing outlet 9 (Fig. 1), and an extended position, in which the closure 21 is spaced from the dispensing outlet 9 (see Fig. 2, Fig. 3, col. 5, ln. 7-21).

47. As to claim 198, the modified inhaler of Fowler discloses that one of said components comprises a pin 22 and the other comprises a slot 25, wherein the pin is captive within the slot and capable of movement within it (see Fig. 3 of Arghyris).

48. As to claim 199, the modified inhaler of Fowler discloses that at least one of the components comprises hinging means (see Arghyris, col. 5, ln. 17-18).

49. **Claims 194, 195, and 200 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler, in view of McNary (US Patent No. 5,899,200).**

50. As to claim 194, Fowler discloses the claimed invention except that the inhaler has a connector which connects the housing and the closure to one another. However, McNary teaches a connector 10 which connects a closure 12 to a housing of an inhaler 1 (col. 2, ln. 46-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Fowler to include the connector as taught by McNary in order to prevent loss of the closure.

51. As to claim 195, the modified inhaler of Fowler discloses that the connector is extensible (see McNary, col. 2, ln. 49-52).

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52. As to claim 200, the modified inhaler of Fowler discloses that the connector is a strap 10 (see McNary, col. 2, ln. 46-49).

Conclusion

53. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Warren (US 3,826,413), Scarrot et al (US 6,953,039), Hansen (US 3,994,421), Oursin et al (US 6,105,826), Armstrong et al (US 5,031,610), and Bryant et al (US 6,460,537).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE L. SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VALERIE L SKORUPA/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771